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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/202,791	12/22/1998	KOUJI MATSUSHIMA	350292000500	3409

7590 12/31/2001  
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EXAMINER

WARE, DEBORAH K

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 12/31/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

## Advisory Action

Application No.

09/202,791

Applicant(s)

Matsushima et al.

Examiner

Ware

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

THE REPLY FILED Oct 15, 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

### THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.
3. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search. (See NOTE below);
- (b) ☐ they raise the issue of new matter. (See NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

4. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_
5. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in separate, timely filed amendment cancelling the non-allowable claim(s).
6. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
Note the Attachment A.
7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):  
Claim(s) allowed: None  
Claim(s) objected to: None  
Claim(s) rejected: 1-29 and 31-44
9. ☐ The proposed drawing correction filed on \_\_\_\_\_ a) ☐ has b) ☐ has not been approved by the Examiner.
10. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
11. ☐ Other: \_\_\_\_\_

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ATTACHMENT A

Claims 1-29 and 31-44 are presented for reconsideration on the merits.

The Supplemental and Request for reconsideration filed October 15, 2001 and September 19, 2001, have been received and entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection under 102(a)/103 over Folkesson et al is maintained for reasons of record.

Applicants' provision of the definition of "septicemia" is respectfully received and considered in view of reconsideration of the instantly filed claims. The reference Applicants take to the Folkesson at page 114, is noted. However, the same paragraph at page 114, also states that there are reasons to believe that anti-IL-8 therapy would not increase the risk of infection. More importantly, at page 107, second column, last full paragraph in the column, IL-8 antibody was shown to be effective in decreasing endotoxin-induced neutrophil influx into the lungs of rabbits, thereby reducing lung injury. Thus, endotoxins can enter into the blood from many sources and IL-8 has shown to decrease its migration into the lungs. Indirect lung injury can result from "septicemia" as defined by Applicants own response and claimed subject matter. Therefore, Folkesson clearly reads on indirect lung injury as well, and furthermore, whether injury is direct or indirect the treatment would inherently be the same.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., aspiration,

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diffuse pulmonary infection, near-drowning, inhalation of irritant gas and lung contusion are direct lung injury, etc.) are not recited in the rejected claim(s).

Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Therefore, while Applicants argue that Folkesson allegedly does not teach indirect lung injury treatment using IL-8 therapy it appear that at the very least in the alternative that such is not the case and that IL-8 therapy for indirect lung injury is clearly suggested by Folkesson. However, the examiner thinks that Folkesson does teach indirect lung injury because of the reference to its effectiveness in decreasing endotoxin-induced neutrophil influx in the lungs of rabbits, page 107, lines 3-6 of second full paragraph. Therefore, based upon this teaching the treatment of indirect injury necessarily flows from Folkesson.

In regard to the 103 alternative rejection, for reasons noted above. At the very least the reference clearly suggests the use of IL-8 for indirect lung injury. The motivation for such treatment provided by the reference in terms of the development of IL-8 by Folkesson. One of skill would have been motivated by the results obtained from development of IL-8 to treat indirect injury to lungs with the expectation of successful results. No where in the reference does it teach specifically as alleged by Applicants that indirect lung injury had no reasonable likelihood of success. The teachings of lidocaine was described in a different reference not cited in this prior art rejection

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Furthermore, the examiner concedes that the reference teaching lidocaine, Nishina et al, provided by Applicants to support their argument regarding art related distinction between direct and indirect lung injury does not add anything to a rejection under 103 regarding the use of IL-8 for treatment. However, the applied reference, Folkesson does teach IL-8 for treatment of lung injury, direct and indirect, as pointed out by the examiner. The facts are presented by Folkesson with regard to the capability of IL-8 therapy. The fact is that IL-8 antibody has been shown to be effective in decreasing endotoxin in the lungs of rabbits. The fact is endotoxin infection is defined by "septicemia" which by Applicants own definition describes indirect lung injury. Thus, the claims remain rejected not only over 102 but also 103.

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is (703) 308-4245. The examiner can normally be reached on Mondays to Fridays from 9:30AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
Deborah K. Ware

December 19, 2001

  
DAVID M. NAFF  
PRIMARY EXAMINER  
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